

APR - 4 1997

**PREMARKET NOTIFICATION****510(k) SUMMARY (continued)**

**TRADE NAMES:** Super-Dent Alginate, Normal set  
Super-Dent Alginate, Fast set  
Super-Dent Super DeLuxe Dustless Alginate, Normal set  
Super-Dent Super DeLuxe Dustless Alginate, Fast set

**COMMON NAME:** Alginate impression material

**CLASSIFICATION NAME:** Material, All, Impression

**EQUIVALENT TO:** Dental Alginate Impression Material;  
510(k) number K883842  
Marketed by Dentsply as JELTRATE in fast and regular set versions

**DESCRIPTION:**

These materials consist of powders which, when mixed with water, form a setting gel suitable for taking impressions of oral tissues.

**INTENDED USE:**

These materials are intended for use in taking impressions of oral tissues for preparation of orthodontic prostheses and to create study models required in designing and fitting of such devices.

**TECHNOLOGICAL CHARACTERISTICS:**

Both materials are powders which, when mixed with water, create a setting gel which is applied to the oral tissues in a rigid tray to create an impression of such tissues. The materials set after mixing by virtue of the reaction between an alginate material and calcium ions to form insoluble calcium alginate. The set materials are compatible with oral tissues and the set is chemically controlled in the interests of patient comfort. The set materials are sufficiently flexible to remove from the mouth readily yet strong enough to withstand subsequent handling. Both materials are compatible with dental plaster and stone model materials.

**PREMARKET NOTIFICATION****510(k) SUMMARY (continued)****NON-CLINICAL DATA:**

Non-clinical tests are in accordance with ISO 1563:1990 and include tests for working time, setting characteristics, strength, flexibility, compatibility with gypsum casting materials and pH.

In all the above tests the subject product is at least comparable to the predicate product.

The subject material is faster setting and stronger when set. Both these enhanced attributes are clear advantages in clinical use.

**CLINICAL DATA:**

There is none applicable

**CONCLUSIONS:**

The data summarised above indicates that the subject device is substantially equivalent to the predicate device.

Any differences in performance result in improvements which reduce the setting time in the interests of patient comfort and increase the compressive strength improving the resistance to damage in handling of the impression.